

Our Case No. 10922/51

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas L. Foster et al.

Serial No. 10/617,580

Filing Date: July 11, 2003

For: FLEXIBLE CANNULA

)
)
) Examiner Nguyen

)
) Group Art Unit No. 3731
)
)

**STATEMENT OF PRIOR INVENTION
UNDER 37 C.F.R. § 1.131**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

We, the undersigned, with addresses and citizenship as stated below, declare of our own knowledge:

1. We declare that we made and conceived the invention described and claimed in United States Patent Application Number 10/617,580, filed in the United States of America on July 11, 2003, entitled FLEXIBLE CANNULA, which claims priority from United States Provisional Application No. 60/395,280, filed on July 12, 2002.

2. We declare that we made and conceived this invention while employed by Cook Urological Incorporated (Cook), that the invention is related to the work we are employed to perform, and the invention was made within the scope of our employment duties. The invention was made and conceived by us prior to November 15, 2001, as disclosed in an invention disclosure consisting of four pages of drawings which are dated prior to November 15, 2001 and attached to this Statement. In addition, the drawings were faxed to a patent attorney at Cook Legal on a date prior to November 15,

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2001. The facsimile cover sheet is dated prior to November 15, 2001, and the header notation of the cover sheet and all four sheets of drawings indicates a transmission date prior to November 15, 2001.

We further declare that our work concerned a flexible cannula for use in a grasper or laser grasper, or other instrument for use in minimally-invasive surgery. The invention was developed in order to provide a surgeon with a more flexible cannula when removing small objects from a patient during surgery. We believe that our invention can be used to allow the surgeon greater ability to maneuver a grasper during surgery, and thus greater freedom of movement when removing small objects. In addition, the flexible cannula may be used for other surgical purposes. For instance, it may be used with other devices to spear and cut objects for removal, such as for a biopsy.

3. As depicted in the drawings, made before November 15, 2001, spiral cuts are made along the length of the cannula to make the cannula flexible. The spiral cuts are made at an angle to the longitudinal axis of the cannula, and may be made at about 80° or at other angles to the axis of the cannula. As depicted in p. 3 of the facsimile, the tubing has a wall thickness of about 0.004 inches ($(.035-.0263)/2 = 0.00435$). As also depicted in p. 3, the spiral cuts are preferably about 0.001 to 0.002 inches deep on the outside of the tubing of which the cannula is made. In our design, the spiral cuts make the cannula flexible, but the cuts are not so deep as to compromise structural soundness for its intended purpose. The drawings and facsimile cover sheet also show that the preferred materials for the cannula are Nitinol or stainless steel tubing.


4. We declare that the invention was made during working hours and with the use of facilities, equipment, materials, funds, information and services of Cook Urological Incorporated at Spencer, Indiana.


5. We declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements

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and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

 8/25/08
Thomas L. Foster (date)
10101 Buckskin Road
Poland, IN 47868

 8/25/08
Frederick D. Roemer (date)
4406 W. Tanglewood Drive
Bloomington, IN 47404

Attachment: Redacted Facsimile Cover Sheet and Drawings

DN-1056

COOK®

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Fax: 812 829-1801
www.cookgroup.com

Fax Transmission

Date:

To:

From:

Number of Pages:

[REDACTED]

Jack Hunt

Tom Tester

5

Jack - The materials (tubing) likely to be
used for this would be:

Nitinol Tubing

Stainless Steel Tubing (Cannula)

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Pc: 4015A

BILL OF MATERIALS CONTROLLED MATERIAL			
DET NO	MATL	DESCRIPTION	ASSY#
1	STD	LASER GRASPER BLANK: R5513-A1	1
2	PUR	TUBING: PINT-30-A	1
3	CH-UNRT	TUBING: WRT-5.0-BE	1
4	STD	CONNECTOR CAP: SABIN 1073-D2	1
5	STD	UNI-DEX HANDLE: R6385-A1	1
6	STD	MODIFIED COLLET KNOB: R2890-A1	1
7	STD	PIN VISE COLLET: R4091-A5	1
8	CH170	TUBING: PETT-100	1
9	STD	CHECK FLO INSERT: R5508-A1	1
10	STD	CHECK FLO ADAPTER: R5571-A3	1
11	PUR	ADHESIVE: LOCTITE 4011	AUR

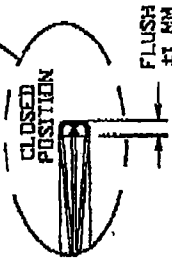
LEGEND	ASSY#	PART NO.
PRODUCT PREFIX	1	
FRENCH SIZE (DIGITS 1-3)		
LENGTH (DIGITS 4-6) (CM)		
UDI-UNDEX HANDLE		

Thru lumen on this one
is used to pass a laser fiber.

Primary
Print

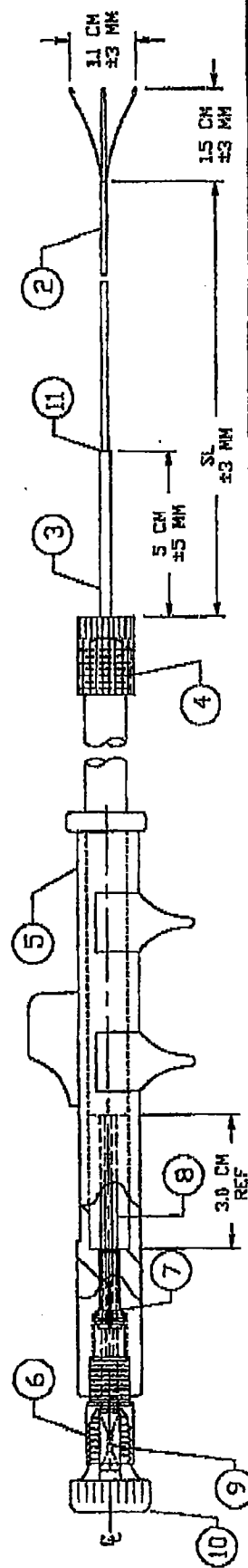
0.018
0.028

0.030
0.050



Preliminary
Print

SL
+15.5 CM
±2 MM



LASER GRASPER

ORIENTATION OF PARTS - PROXIMAL LEFT - DISTAL RIGHT			
SCALE: FULL	DATE: [REDACTED]	REV: 0	BY: NR
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ALL DIMENSIONS IN INCHES, UNLESS OTHERWISE NOTED			
ALL TOLERANCES UNLESS OTHERWISE NOTED			
DRAWING NO. E5673RD			

DISTRIBUTION
BASKETS-1
BASKETS OC-1
R8D-1

Proj 4015 A

PURCHASING

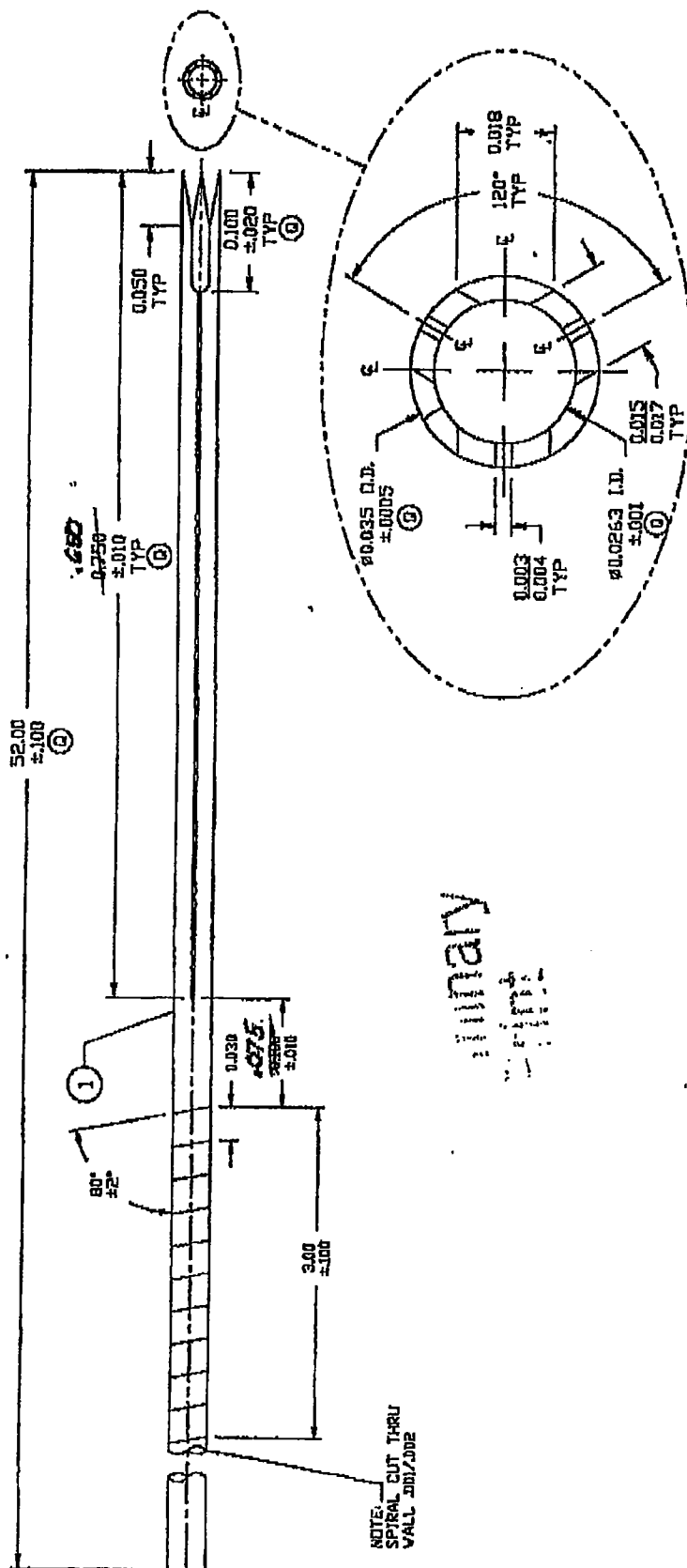
1. SEND TUBING TO VENDOR TO BE LASER CUT PER DWG.

INCOMING QD.

FREQUENCY 2%

1. CHECK ALL "Q" DIMENSIONS.

BILL OF MATERIALS		
CONTROLLED MATERIAL		
DET	MATL	DESCRIPTION
1	CH1000	CANNULA-20.5G
1	1	2
1	1	1



DISTRIBUTION
BASKETS-1
BASKETS QC-3
EXTERNAL/COCKING-1
INCOMING QC-1
PURCHASING-1
R&D-1

LASER CUT BLANK

REVISIONS OF PARTS - PREVIOUS LEFT - INITIAL RIGHT
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SCALE: 1:1	DATE: 11/11/01	PREP: M2	DRWN: M2
ALL DIMENSIONS IN INCHES UNLESS OTHERWISE NOTED		SHEET 1 OF 1	
CONTR. UROLOGICAL		R5674RD	

REV	BY	REASON
1	NR	

Thru. lumen on this PRELIMINARY one NOT used. - Just a small dia flexible grasper

More flexible than other graspers
Far easier to mfg than other graspers
(no soldering ect.)

Tip detail
± 1mm

Proj 4214

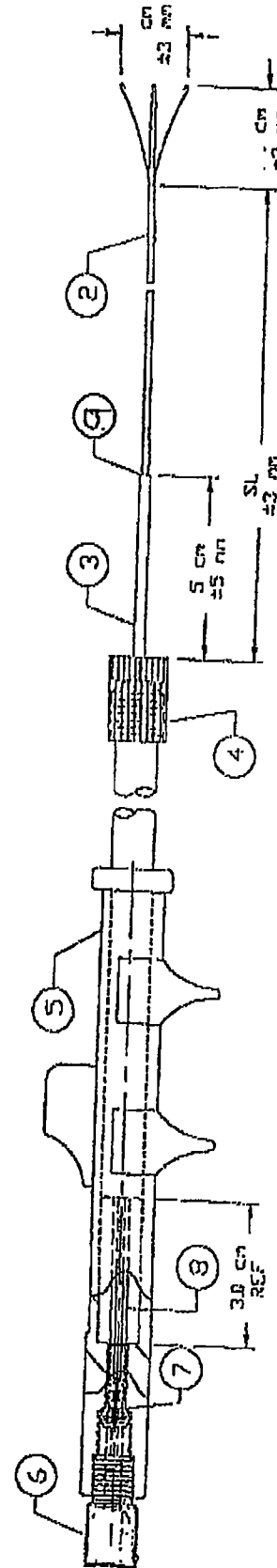
BILL OF MATERIALS		CONTROLLED MATERIAL	
DET NO	Description	Part No	QTY
1	STD Flexible Grasper Blank		1
2	PUR Tubing		1
3	CHART Tubing VIRT-		1
4	STD Connector Cap: 5/16 in 1023		1
5	STD Uni-dex Handle: R5385-A1		1
6	STD Collet Knob: R2455-A1		1
7	STD Pin Vise Collet: R4011-A1		1
8	CHART Tubing: PET-100		1
9	PUR Adhesive: Loctite 4011		1

LEGEND
PRODUCT PREFIX
FRENCH SIZE (DIGITS 1-3)
LENGTH (DIGITS 4-5) (CM)
UDI-INDEX HANDLE

Part No	Part No
1	FG-022115-UPH

1

SL
± 5 cm
± 1 mm



2.2FR FLEXIBLE GRASPER

ORIENTATION OF PARTS - PROXIMAL LEFT - DISTAL RIGHT	
SCALE	FULL
DATE	
PROJ NO	
DRAWN	NR

REV	BY	REASON
0	NR	

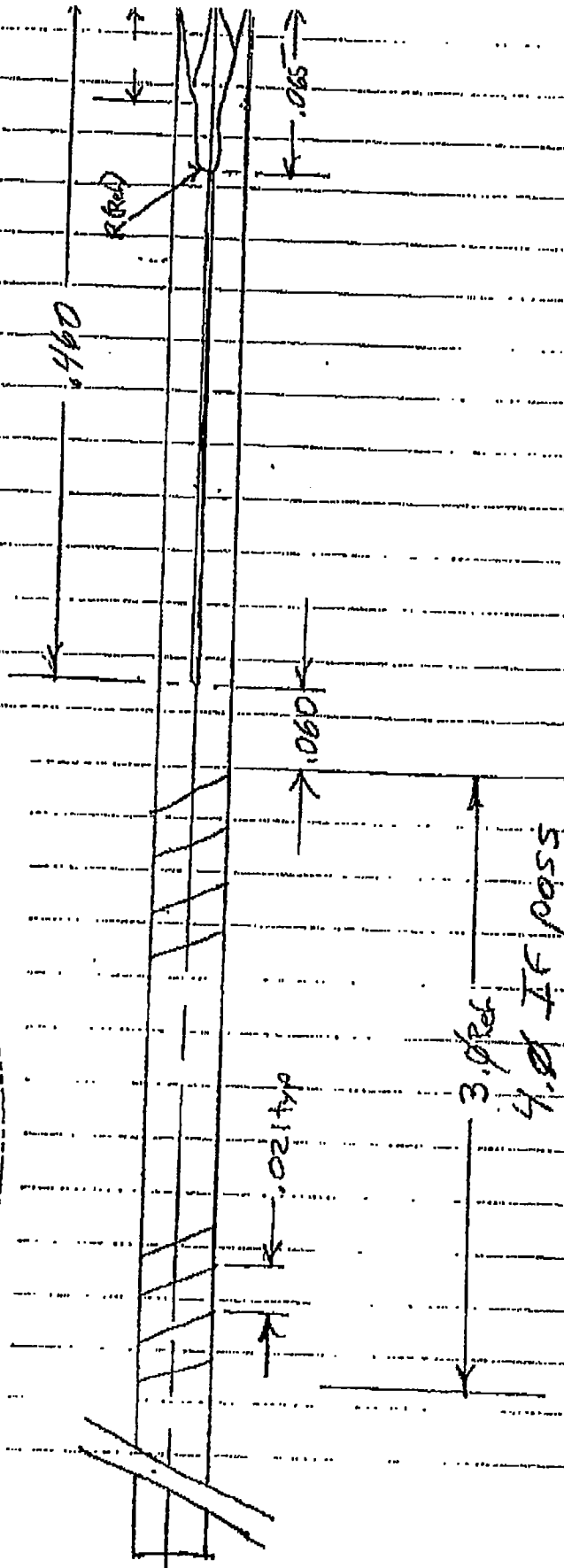
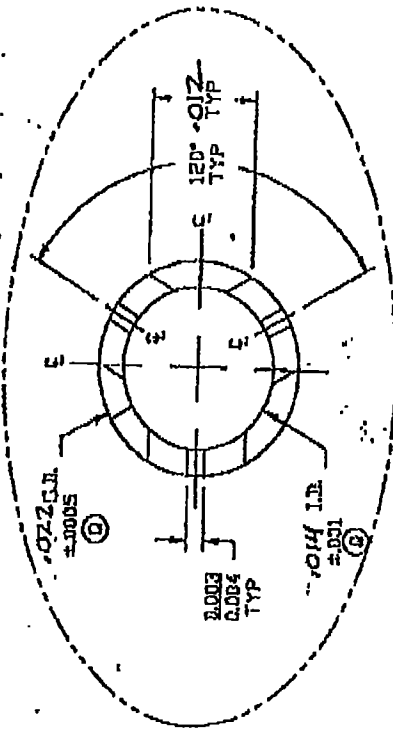
UTION
IS-1
SQC-1
1-1

ALL DIMENSIONS IN INCHES - ALL TOLERANCES UNLESS OTHERWISE NOTED	
COOK UROLOGICAL	SHIT 1 OF 1
INDIANA 47418	DRAWING NO

SK061201-TF

SK061201-TF

Part 4214
Flexible grasper
(24G TW Cannula)



[Handwritten signature]